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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,521	12/20/2001	Scott Powers	018781-004730US	6455

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TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

EXAMINER
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LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/028,521	Applicant(s) POWERS ET AL.	
	Examiner Ruixiang Li	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 12-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/7/02;3/13/03;3/31/06</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group II, claims 7-11, drawn to and isolated polypeptide of SEQ ID NO: 18, in the reply filed on 07/10/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-34 are pending. Claims 7-11 are currently under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 07/10/2006.

### ***Information Disclosure Statement***

2. The information disclosure statements filed on 05/07/2002, 03/13/2003, and 03/31/2006 have been considered by the examiner.

### ***Drawings***

3. The drawings filed on 12/20/2001 are objected because the labels in Figs. 1-4 are written by hand. In addition, Fig. 1 and Fig. 3 are tables, not drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the

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sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### ***Objection to Title***

4. The title of the invention is objected to because of the use of the word "novel", which begs the novelty of issued U. S. Patents. Any invention, when patented, is novel. There is no need to say it again in the title. It is suggested that the word "novel" be deleted from the title.

#### ***Objection to disclosure***

5. The disclosure is objected to because it contains an embedded hyperlink (see, e.g., page 20, line 5). Applicant is required to delete the embedded hyperlink. See MPEP § 608.01.

***Rejections—35 USC § 101***

6. 35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 7-11 are rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 7-11 are drawn to an isolated polypeptide comprising greater than 95%, 97%, and 99% amino acid sequence identity to the amino acid sequence of SEQ ID NO: 18. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a “real world” context of use for the claimed invention which does not require further research.

The instant specification discloses the polypeptide of SEQ ID NO: 18 and the nucleic acid of SEQ ID NO: 17 encoding the polypeptide. Nonetheless, the instant disclosure fails to provide any sufficient information or evidence on the specific biological functions or physiological significance of the polypeptides of the present invention and fails to disclose a patentable utility for the claimed invention.

First, the invention lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification’s disclosure of the properties of a material. The sequence and prior art search does not reveal that the polypeptide of SEQ ID NO: 18 has any well-established biological functions or any physiological significance. No art of

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record discloses or suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the claimed invention.

Secondly, the present invention does not disclose a specific and substantial utility. The amino acid sequence of SEQ ID NO: 18 is the subsequence of BCA-GPCR-3 depicted in SEQ ID NO: 6, i.e., amino acids 4 to 340 of SEQ ID NO: 6 (the 3<sup>rd</sup> paragraph of page 9). The specification asserts that human BCA-GPCR-3 is amplified at least about 3-7 fold in about 15% of primary breast tumors and tumor cell lines (Fig. 1). The specification also asserts that BCA-GPCR-3 mRNA levels are elevated in breast cancer cell lines from both amplified and non-amplified tumors (Figs. 2-3). The specification further disclosed that BCA-GPCR-3 mRNA is overexpressed in primary prostate cancer (Fig. 4). However, the specification fails to disclose that the expression level of polypeptide of SEQ ID NO: 18 is elevated and can be used in the diagnosing breast cancer or prostate cancer. The art teaches that it is unpredictable whether the expression level of a given protein correlates with its mRNA level. For example, Chen et al. teach discordant protein and mRNA expression in lung adenocarcinomas (*Molecular & Cellular proteomics* 1:304-313, 2002). Clearly, further research would be required to identify whether the protein expression level is associated with breast cancer or prostate cancer. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

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Accordingly, the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility.

8. Claims 7-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections—35 USC § 112, 1<sup>st</sup> paragraph***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 7-9 are drawn to an isolated polypeptide comprising greater than 95%, 97%, and 99% amino acid sequence identity to the amino acid sequence of SEQ ID

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NO: 18. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, nor other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by a partial structure in the form of a recitation of percent identity.

The instant disclosure of an isolated polypeptide of SEQ ID NO: 18 and its encoding nucleic acid molecule set forth in SEQ ID NO: 17 does not adequately support the scope of the claimed genus, which encompasses a substantial variety of homologues or variants of the polypeptide of SEQ ID NO: 18. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). While disclosing the amino acid sequence of SEQ ID NO: 18, the instant disclosure fails to provide sufficient description information, such as definitive structural or functional features of the claimed genus of polypeptides. The prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed polypeptides as being identical to those instantly claimed.

Due to the breadth of the claimed genus and lack of the definitive structural or functional features of the claimed genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus. Accordingly, only the isolated polypeptide comprising SEQ ID NO: 18, but not the full



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breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

***Claim Rejections—Nonstatutory Obviousness-Type Double Patenting***

**11. Basis for nonstatutory double patenting:**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**12. Claims 7-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 and 2 of U.S. Patent No. 6,635,741 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the polypeptide recited in U.S. Patent No. 6,635,741 B1 fall entirely within the scope of the examined claim. Therefore, the patented claims are related to the instant claims as species to genus. A patented species renders its genus obvious and thus anticipates the genus.**

***Claim Objection —Minor Informalities***

**13. Claims 7-11 are objected to because it recites non-elected subject matter, i.e., amino acid sequences other than SEQ ID NO: 18. Appropriate correction is required.**

**Conclusion**

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

*Ruixiang Li*

Ruixiang Li, Ph.D.  
Primary Examiner  
September 23, 2006

RUIXIANG LI, PH.D.  
PRIMARY EXAMINER